said gum ghatti, 40 percent by weight of said arabin galactan, and 20 percent by weight of said aloe vera extract.

C15 46. A dietary supplement composition for providing nutritional product saccharides, which saccharides are essential components of glycoproteins in a mammal, said dietary supplement composition comprising nutritionally effective amounts of aloe vera extract, gum ghatti, tragacanth gum, glucosamine, corn starch and arabinogalactan.

Sub E' cont 47. A dietary supplement composition according to claim 46, wherein said composition comprises 10 percent by weight of said aloe vera extract, 10 percent by weight of said gum ghatti, 10 percent by weight of said tragacanth gum, 10 percent by weight of said glucosamine, 12 percent by weight of said corn starch and 48 percent by weight of said arabinogalactan.

REMARKS

Claims 1, 6-17 and 22-47 are pending herein.

Applicants wish to thank Examiner Flood for the courtesies extended during the personal interview conducted on October 12, 2001. Proposed claim 1 as discussed during the interview is presented for consideration herein. As noted in the Examiner Interview Summary Record, proposed claim 1 is responsive to the Office action mailed February 7, 2001 and, therefore, it is respectfully submitted that the response filed on July 12, 2001, which is substantially repeated herein, is fully responsive to the outstanding Office action. In addition, it is respectfully submitted that new claims 22-47 herein are drawn to the originally examined invention. Accordingly, it is respectfully submitted that this response supplies the correction called for by the Communication mailed September 20, 2001. Favorable consideration of claims 1, 6-17 and 22-47 is, therefore, respectfully requested.

Claims 18-21 have been cancelled without prejudice or disclaimer. Claims 1 and 6-17 have been amended, more particularly, to point out, the claimed subject matter. Claims 22-47 have been added. It is respectfully submitted that pending claims 1, 6-17 and 22-47 are in full compliance with the broad dictates of 35 U.S.C. § 112. Favorable consideration of claims 1, 6-17 and 22-47 are respectfully requested.

The specification has been amended to correct a factual error in that the identification of constituent saccharides for gum tragacanth listed on Table 3 of the application is incorrect. Specifically, as is well known in the art, gum tragacanth contains galacturonic acid, galactose, fucose, xylose, arabinose, and rhamnose rather than galacturonic acid and sialic acid, see the excerpt from the *Merck Index* attached as Exhibit A and the excerpt from the *Handbook of Water-Soluble Gums and Resins* attached as Exhibit B. It is respectfully submitted that the constituent saccharides of gum tragacanth are well known by those of ordinary skill in the art and Applicants therefore request that the amendment of the specification be entered into the application.

Claims 1, 8-10 and 15-17 stand rejected under 35 U.S.C. §112, second paragraph, for indefiniteness. Insofar as it may be applied against the present claims, this rejection is respectfully traversed.

Claims 8, 10, 15, and 17 have been amended to overcome the rejection under 35 U.S.C. §112. The pending Office action did not state a rejection of claim 1 under 35 U.S.C. §112. For the foregoing reasons it is respectfully requested that the rejection of claims 1, 8-10 and 15-17 under 35 U.S.C. §112, second paragraph, be withdrawn.

Claims 6-7, 9, 11-14 and 16 have been amended solely to provide proper antecedent basis for certain terms in such claims.

When read in light of the specification, Applicant submits that none of the foregoing amendments narrow the claims with regard to the claimed dietary supplement compositions.

Claim 1 stands rejected under 35 U.S.C. §102(b) over Japanese Patent Reference No. 57007420 to Yamasa Shoyu Co., Ltd. ("Yamasa '420"). Insofar as it may be applied against the present claims, this rejection is respectfully traversed.

Attached as Exhibit C is a complete English translation of Yamasa '420 prepared by Technical Translation Service of Willoughby, Ohio. As noted therein, Yamasa '420 discloses an antitumor agent that contains as an active ingredient a cell wall component of mold belonging to the *Aspergillus* genus. As is well known in the art, cell walls contain saccharides and in the case of the mold *Aspergillus oryzae*, Yamasa '420 discloses that the cell walls contain saccharides including glucose, mannose, galactose, ribose, arabinose, glucosamine and galactosamine.

Yamasa '420 discloses that the cell walls of *Aspergillus oryzae* were analyzed by hydrolyzing the cell walls with sulfuric acid and then neutral sugars were quantified by the Petri

method and amino sugars were quantified by an amino acid automatic analyzer. The results of such analysis indicated that the cell walls included a neutral sugar quantity of 61% made up of glucose, mannose, galactose, ribose and arabinose, an amino sugar quantity of 19.9% made up of glucosamine and galactosamine and a crude protein quantity of 7.4% for a total of 88.3% - leaving the remaining 11.7% undefined and unidentified. It is important to note that the saccharide content of the cell walls of *Aspergillus oryzae* were identified as a result of the analysis of such cell walls.

In contrast, the antitumor agent that contains as an active ingredient a cell wall component of mold belonging to the *Aspergillus* genus does not result in the hydrolyzation of such cell walls to yield individual bioavailable saccharides. Instead, according to Yamasa '420, the cell wall component is prepared for administration in accordance with known cultivation, separation and refinement methods. The cultivation methods disclosed by Yamasa '420 include liquid cultivation methods such as liquid surface cultivation methods, in-liquid cultivation methods including shaking, cultivation and deep cultivation as well as solid cultivation methods using agar, nylon paste, asbestos or sponge as the cultivation base, as well as mixed cultivation methods in which the two are combined. The mold is then separated and removed from the cultivation matter by "ordinary methods" such as centrifugal separation, filtration, tilting or pressure rods. The mold is then pulverized by physical methods using a homogenizer, dynomill or French press. The cell walls are then prepared from the pulverized mold by elution of the contents in the mold. Yamasa '420 discloses that water, salt solutions, acids, organic solvents and surfactants can be used alone or in combinations thereof as the eluate. According to Yamasa '420 the cell wall component is obtained by centrifugal separation or filtration of the mold suspension, and the eluate is removed by rinsing or dialysis. Finally, the cell wall component, in a form to be used as the active ingredient, is obtained by drying the rinsed cells by spray drying, air drying, freeze drying or vacuum drying. The cell wall component can also be further refined by sterilization such as by boiling, evaporation, drying, irradiation and ultraviolet rays.

Accordingly, Yamasa '420 discloses a cell wall component of mold that upon hydrolysis is revealed to include various saccharides, crude protein and other unidentified constituents. Contrary to the claimed composition, which provides nutritionally effective amounts of nutritional product saccharides, the cell wall component of Yamasa '420 includes covalently bound saccharides, which are not bioavailable. Indeed as noted in the present application at page 27, lines 1-4:

"The body hydrolyzes complex polysaccharides such as plant carbohydrates into various monosugars and restructures them into oligosaccharides that are then used by the body to build the glycoproteins required by cytokines for cellular communication and, thus, for good health."

Moreover, claim 1 has been amended to specify that the claimed dietary supplement compositions comprise at least six saccharides selected from a first group of saccharides and a second group of saccharides in which the composition includes at least one saccharide selected from each of the first group of saccharides and the second group of saccharides. Yamasa '420 does not disclose or suggest a dietary supplement composition that comprises at least six such saccharides.

Accordingly, for the foregoing reasons, it is respectfully submitted that Yamasa '420 does not disclose or suggest the claimed dietary supplement compositions. The rejection of claim 1 under 35 U.S.C. §102(b) over Yamasa '420 should therefore be withdrawn. When read in light of the specification, Applicant submits that none of the foregoing amendments narrow the claims with regard to the claimed dietary supplement compositions.

Claims 1 and 6-7 stand rejected under 35 U.S.C. §102(b) over U.S. Patent No. 3,890,438 to Cayen et al. ("Cayen '438"). Insofar as it may be applied against the present claims, this rejection is respectfully traversed.

Cayen '438 discloses pharmaceutical compositions for lowering blood cholesterol that include a mixture of diosgenin or a related diosgenin derivative and a 4-substituted phenoxyisobutryic acid or an ester or salt thereof. Cayen '438 discloses that suitable pharmaceutical formulations include tablets comprising: (a) the above-noted compositions, (b) known pharmaceutical carriers and excipients such as starch, sugars and lubricants, suspensions or syrups comprising the above-noted compositions, and (c) suspending agents such as water soluble gums.

Contrary to the claimed dietary supplement compositions, however, Cayen '438 does not disclose or suggest a dietary supplement composition that comprises at least six saccharides.

Accordingly, for the foregoing reasons, it is respectfully submitted that Cayen '438 does not disclose or suggest the claimed dietary supplement compositions. The rejection of claims 1 and 6-7 under 35 U.S.C. §102(b) over Cayen '438 should therefore be withdrawn. When read in light of the

specification, Applicant submits that none of the foregoing amendments narrow the claims with regard to the claimed dietary supplement compositions.

Claims 1, 6, 9-10 and 18-19 stand rejected under 35 U.S.C. §102(e) over U.S. Patent No. 5,202,122 to Graves et al. ("Graves '122"). Insofar as it may be applied against the present claims, this rejection is respectfully traversed.

Graves '122 discloses a process for enhancing the natural bile acid binding capacity of edible pulp material, which is also referred to as dietary fiber. Graves '122 discloses that the major constituents of dietary fiber include cellulose, hemicellulose, lignin and pectin. Graves '122 also discloses at column 6, lines 37-42 that pectin comprises the neutral sugars D-galactose, L-arabinose, D-xylose and L-fucose.

Contrary to the claimed dietary supplement compositions, however, Graves '122 does not disclose or suggest a dietary supplement composition that comprises at least six saccharides.

Accordingly, for the foregoing reasons, it is respectfully submitted that Graves '122 does not disclose or suggest the claimed dietary supplement compositions. The rejection of claims 1, 6, 9-10 and 18-19 under 35 U.S.C. §102(e) over Graves '122 should therefore be withdrawn. When read in light of the specification, Applicant submits that none of the foregoing amendments narrow the claims with regard to the claimed dietary supplement compositions.

Claims 1, 6-7 and 20-21 stand rejected under 35 U.S.C. §102(b) over Japanese Patent Reference No. 59112922 to Endoh ("Endoh '922"). Insofar as it may be applied against the present claims, this rejection is respectfully traversed.

Attached as Exhibit D is a complete English translation of Endoh '922 prepared by Technical Translation Service of Willoughby, Ohio. As noted therein, Endoh '922 discloses a blood sugar reduction agent that contains as an active ingredient a saccharide selected from a group of polysaccharides that are difficult to digest produced by plants or animals, and derivatives thereof. Endoh '922 discloses several examples of polysaccharides that are difficult to digest. Endoh '922 further discloses implementation examples of the blood sugar reduction agents that are comprised of a single one of the difficult to digest polysaccharides.

Contrary to the claimed dietary supplement compositions, however, Endoh '922 does not disclose or suggest a dietary supplement composition that comprises at least six saccharides.

Accordingly, for the foregoing reasons, it is respectfully submitted that Endoh '922 does not disclose or suggest the claimed dietary supplement compositions. The rejection of claims 1, 6-7 and 20-21 under 35 U.S.C. §102(b) over Endoh '922 should therefore be withdrawn. When read in light of the specification, Applicant submits that none of the foregoing amendments narrow the claims with regard to the claimed dietary supplement compositions.

Claim 11 stands rejected under 35 U.S.C. §103(a) over Endoh '922 or Cayen '438 in view of U.S. Patent No. 4,260,603 to Pegel et al. ("Pegel '603"). Insofar as it may be applied against the present claims, this rejection is respectfully traversed.

Claim 11 depends from and includes all of the subject matter of Claim 1. The deficiencies of Endoh '922 and Cayen '438 with respect to the subject matter of Claim 1 are noted above and are equally applicable to claim 11.

Pegel '603 discloses a medicament having prostaglandin-synthetase inhibiting activity. The medicament is disclosed to contain as an active principle sterolglycosides and/or their esters and/or spiroketal steroid glycosides and/or esters thereof. Contrary to the Office action, Pegel discloses at Column 5, lines 1-38 a process for the production of sitosterol – ß – D – glucoside not a sitosterol - ß –glucoside of diosgenin. Also, in contrast to the claimed dietary supplement compositions, Pegel '603 does not disclose or suggest a dietary supplement composition that comprises at least six saccharides.

Accordingly, even if it would be proper to combine the disclosures of Endoh '922, Cayen '438 and Pegel '603, the combination would not result in the claimed dietary supplement compositions since none of the references disclose or suggest a dietary supplement composition that comprises at least six saccharides.

For the foregoing reasons, it is respectfully submitted that Endoh '922 or Cayen '438 in view of Pegel '603, alone or in combination, do not disclose or suggest the claimed dietary supplement compositions. The rejection of claim 11 under 35 U.S.C. §103(a) over Endoh '922 or Cayen '438 in view of Pegel '603 should therefore be withdrawn.

Claims 12-17 stand rejected under 35 U.S.C. §103(a) over Graves '122, Endoh '922 and Cayen '438 in view of U.S. Patent No. 5,607,693 to Bonte et al. ("Bonte '693") and further in view of The "Prescription for Nutritional Healing" by Balch et al. ("Balch"). Insofar as it may be applied against the present claims, this rejection is respectfully traversed.

Claims 12-17 depend, directly or indirectly, from and include all of the subject matter of Claim 1. The deficiencies of Graves '122, Endoh '922 and Cayen '438 with respect to the subject matter of Claim 1 are noted above and are equally applicable to claims 12-17.

Bonte '693 discloses a cosmetic composition for stimulating hair growth, retarding hair loss or combating pruritis, which includes as an active ingredient, a cosmetically effective amount of oxyacanthine. In certain embodiments, the composition may also include a saponin. In contrast to the claimed dietary supplement compositions, however, Bonte '693 does not disclose or suggest a dietary supplement composition that comprises at least six saccharides.

The Balch reference consists of several extracts from a work entitled "Prescription for Nutritional Healing: A Practical A to Z Reference to Drug-Free Remedies Using Vitamins, Minerals, Herbs & Food Supplements." The Balch reference appears to be a general guide to the bodily function and source of a multitude of vitamins, herbs and food supplements. Balch indeed discloses that vitamins are essential to life and that every living cell on the planet depends on minerals for proper function and structure, however, Balch does not attribute such a lofty status to the antioxidant melatonin. Furthermore, in contrast to the claimed dietary supplement compositions, Balch does not disclose or suggest a dietary supplement composition that comprises at least six saccharides.

Accordingly, even if it would be proper to combine the disclosures of Graves '122, Endoh '922, Cayen '438, Bonte '693 and Balch the combination would not result in the claimed dietary supplement compositions since none of the references disclose or suggest a dietary supplement composition that comprises at least six saccharides.

For the foregoing reasons, it is respectfully submitted that Graves '122, Endoh '922, Cayen '438, Bonte '693 and Balch, alone or in combination, do not disclose or suggest the claimed dietary supplement compositions. The rejection of claims 12-17 under 35 U.S.C. §103(a) over Graves '122, Endoh '922 and Cayen '438 in view of Bonte '693 and further in view of Balch should therefore be withdrawn.

Claims 8-9 stand rejected under 35 U.S.C. §103(a) over Graves '122 in view of U.S. Patent No. 5,308,838 to McAnalley et al. ("McAnalley '838"). Insofar as it may be applied against the present claims, this rejection is respectfully traversed.

Claims 8-9 depend, directly or indirectly, from and include all of the subject matter of Claim 1. The deficiencies of Graves '122 with respect to the subject matter of Claim 1 are noted above and are equally applicable to claims 8-9.

McAnalley '838 discloses that acemannan, the active component of the purified ethyl alcohol extract of the inner gel of the leaves of *Aloe barbadensis* Miller, has direct stimulatory effects on the immune system and directly interacts with virus or other infectious organisms, infected cells, and tumor cells. McAnalley '838, however, does not disclose or suggest a dietary supplement composition that comprises at least six saccharides.

Accordingly, even if it would be proper to combine the disclosures of Graves '122 and McAnalley '838, the combination would not result in the claimed dietary supplement compositions since neither of the references disclose or suggest a dietary supplement composition that comprises at least six saccharides.

For the foregoing reasons, it is respectfully submitted that Graves '122 and McAnalley '838, alone or in combination, do not disclose or suggest the claimed dietary supplement compositions. The rejection of claims 8-9 under 35 U.S.C. §103(a) over Graves '122 in view of McAnalley '838 should therefore be withdrawn. When read in light of the specification, Applicant submits that none of the foregoing amendments narrow the claims with regard to the claimed dietary supplement compositions.

For all of the foregoing reason, it is respectfully submitted that claims 1, 6-17 and 22-47 are in condition for allowance. Favorable reconsideration and allowance of claims 1 and 6-17 and favorable consideration and allowance of claims 22-47 are respectfully requested.

Respectfully submitted,

Date: 10/22/01

Randall C. Brown
Registration No. 31,213
Attorney for Applicants

AKIN, GUMP, STRAUSS, HAUER
& FELD, L.L.P.
P.O. Box 288
Dallas, Texas 75313-0688
(214) 969-2800
#515623v1; 013258.0172

Attorney Docket No.
013258.0172

ATTACHMENT A
MARKED-UP VERSION

In the Specification

The following paragraph, beginning on page 11, line 6, and ending on page 11, line 24, is amended as indicated below. Additions to the specification are shown with double underlining, so as to distinguish such additions from the text that appeared underlined in the specification as filed.

Table 3. Natural sources of saccharides.

Source Carbohydrate	Corresponding Saccharide(s)
gum tragacanth	galacturonic acid, galactose, fucose, xylose, arabinose and rhamnose [galacturonic acid and sialic acid]
guar gum	mannose and galactose (1:2 molar ratio)
rice or grain flour	glucose
LAREX B-1000 (Larch tree extract)	polyarabinogalactan
MANAPOL™ (aloe vera extract)	acetylated mannose based polymer
gum ghatti	arabinose, galactose, mannose, xylose, glucuronic acid (10:6:2:1:2 molar ratio)
starch	glucose
pectin	galacturonic acid
chondroitin sulfate	N-acetylgalactosamine
chitin	N-acetylglucosamine

Source Carbohydrate	Corresponding Saccharide(s)
acacia, gum arabic	arabinose, galactose, glucuronic acid
alginic acid	mannosyluronic acid, gulosyluronic acid
carrageenan	galactose, 3,6-anhydrogalactose
dextran	glucose
xanthan gum	glucose, mannose, glucuronic acid

The following paragraph, beginning on page 12, line 5, and ending on page 12, line13, is amended as indicated below.

As used herein, the term "carbohydrate" is used interchangeably with the terms "saccharide", "polysaccharide", "oligosaccharide" and "sugar" the definitions of which are well known in the art of carbohydrate chemistry. Although the compositions of the invention are intended to include at least one of the eleven essential saccharides, it should be noted that the saccharides can be in the form of mono-, oligo- and/or polysaccharides, e.g. a composition containing gum tragacanth and guar gum will be considered as containing galacturonic acid, [sialic acid], fucose, xylose, arabinose, rhamnose, mannose and galactose. Therefore, by controlling the amount of particular gums in a given dietary supplement, one can control the amount of the respective saccharides in said dietary supplement.

The following paragraph, beginning on page 17, line 3, and ending on page 17, line 14, is amended as indicated below.

EXAMPLE 1

A suitable composition for a product according to the present invention is as follows: tragacanth gum (100 kg), a source of galacturonic acid [and sialic acid (N-acetylneuraminic acid)] ,galactose, fucose, xylose, arabinose and rhamnose is charged into a stainless steel ribbon

blender and guar gum (10 kg), a source of mannose and galactose, is charged into the stainless steel ribbon blender. The mixture of tragacanth gum and guar gum is mixed for five (5) minutes. Then 250 grams of Aerosil 380™ (silica gel) is added to the mixture as a flowing agent and 200 kilograms of rice flour, a source of glucose, is added as a gluten-free filler. The mixture is then agitated for fifteen (15) minutes. Finally, 100 grams of calcium stearate is added to the mixture as a lubricant and the mixture is agitated for an additional three (3) minutes to generate a bulk powder. The powder is then encapsulated into size 1 gelatin capsules at a fill weight of 250 mg using a Model 8 (Elanco) capsule filling machine.

In the Claims

The following claims 1, 8, 10, 15, and 17 are amended as indicated below.

1. (Twice Amended) A dietary supplement composition for providing nutritional product saccharides in monomeric, oligomeric or polymeric and derivatized or underivatized form, which saccharides are essential components of glycoproteins in a mammal, said dietary supplement composition comprising [a composition consisting of] nutritionally effective amounts of at least six saccharides, wherein said saccharides are [:

at least one saccharide] selected from a first group of saccharides consisting of:

galactose, glucose, mannose, xylose and acetylated mannose; and

[at least one saccharide selected from] a second group of saccharides consisting of:

N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine, arabinose, glucuronic acid, galacturonic acid, iduronic acid [,] and arabinogalactan;

wherein said composition comprises at least one saccharide selected from said first group of saccharides and at least one saccharide selected from said second group of saccharides.

6. (Twice Amended) A dietary supplement composition according to claim 1, wherein at least one of said saccharides is provided in oligomeric or polymeric form as found in at least one of:

gum tragacanth, guar gum, grain flour, rice flour, sugar cane, beet sugar, potato, milk, agar, algin, locust bean gum, psyllium, karaya gum, seed gums, Larch tree extract, aloe

vera extract, gum ghatti, starch, cellulose, degraded cellulose, fructose, high fructose corn syrup, pectin, chitin, acacia, gum arabic, alginic acid, carrageenan, dextran, xanthan gum, chondroitin sulfate, sucrose, acetylated polymannose, maltose, glucan, lentinan, mannan, levan, hemi-cellulose, inulin, fructan, and lactose.

7. (Twice Amended) A dietary supplement composition according to claim 1, further comprising a nutritionally effective amount of dioscorea complex.

8. (Twice Amended) A dietary supplement composition according to claim 1, further comprising a nutritionally effective amount of a blend [consisting] of [ripened and] freeze-dried and powdered raw fruits and vegetables.

9. (Amended) A dietary supplement composition according to claim 8, further comprising nutritionally effective amounts of xanthines and herbal body-toning agents.

10. (Amended) A dietary supplement composition according to claim 8, wherein said blend [consisting] of [ripened and] freeze-dried and powdered raw fruits and vegetables comprises:

broccoli, brussel sprouts, cabbage, carrot, cauliflower, garlic, kale, onion, papaya, pineapple, tomato and turnip.

11. (Amended) A dietary supplement composition according to claim 7, further comprising a nutritionally effective amount of beta sitosterol.

12. (Twice Amended) A dietary supplement composition according to claim 1, further comprising a nutritionally effective amount of melatonin.

13. (Twice Amended) A dietary supplement composition according to claim 1, further comprising an effective amount of a saccharide bioabsorption aid.

14. (Amended) A dietary supplement composition according to claim 13, wherein the bioabsorption aid comprises soy lecithin.

15. (Twice Amended) A dietary supplement composition according to claim 1, further comprising nutritionally effective amounts of a dioscorea complex and a blend [consisting] of [ripened and] freeze-dried and powdered raw fruits and vegetables.

16. (Twice Amended) A dietary supplement composition according to claim 1, further comprising nutritionally effective amounts of non-toxic vitamins and minerals.

17. (Amended) A dietary supplement composition according to claim 16, wherein:

said vitamins comprise A, B1, B12, B2, B6, beta carotene, bioflavanoids, biotin, C, choline, D, E, folic acid, inositol, K, niacinamide, para-aminobenzoic acid, and [panthothenic] pantothenic acid; and

said minerals comprise boron, calcium, copper, GTF chromium, iodine, iron, magnesium, manganese, molybdenum, potassium, selenium, silicon, vanadium [,] and zinc.